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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/359,527	07/22/99	WEBB P	10990641-1

HM12/1004

IP ADMINISTRATION
LEGAL DEPARTMENT 20BN
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EXAMINER	
LUNDGREN, J	
ART UNIT	**PAPER NUMBER**
1631	4

DATE MAILED: 10/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No.	Applicant(s)	
	09/359,527	WEBB ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Lundgren	1631	

-- Th MAILING DATE of this communication appears on the cover sh t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *21-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2, 3* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-20, are drawn to a method of fabricating an addressable array of biopolymer probes, classified in class 536, subclass 23.1.

   II. Claims 21-45, are drawn to an apparatus for fabricating an addressable array, and computer program product therefor, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process of error detecting can be carried out manually.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Mr. Stewart on September 15, 2000 a provisional election was made with traverse to prosecute the invention of Group I,

claims 1-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

The information disclosure statement filed on July 22, 1999, and December 1, 1999, were considered. References either not supplied (1L), not supplied in English, not supplied beyond the abstract with relevance as it pertains to the application, or not supplied so that the reference can be identified on the Information Disclosure Statement were lined through and not considered. See MPEP § 609 for proper filing procedures and the minimum requirements of an Information Disclosure Statement.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-19 are indefinite for failing to recite a final process step which agrees back with the preamble. While minor details are not required in method/process claims, at least the basic steps must be recited in a positive, active fashion. See *Ex parte Elrich*, 3 USPQ2d, p. 1011 (Bd. Pat App. Int. 1986). For example, claims 1 and 18, are

drawn to a method of fabricating an addressable array of biopolymer probes on a substrate, yet the claims recite a final step of deriving, based on the error, a corrected drive pattern different from the target drive pattern such that use of the corrected drive pattern results in a reduced discrepancy between the target and actual array patterns. The claims do not set forth the conditions/state when the method has provided the probes on the substrate in the target array pattern.

Claim 7 recites the limitation "the drive" in the step where a position encoder is used (i.e., it is not clear if Applicant is claiming the target or corrected drive pattern, or another drive pattern). There is insufficient antecedent basis for this limitation in the claim

Claim 15 recites the limitation "the accuracy" in the step where a position encoder is used. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 recites the limitation "the accuracy in an ability" in the step where a position encoder is used. There is insufficient antecedent basis for this limitation in the claim.

Claim 20 is indefinite for reciting the term “based upon the observation” as the skilled artisan would not reasonably be able to determine the meets and bounds of the “basis”, wherein a specific relationship between the fiducial mark, the nozzle, and the substrate is used.

Claim 20 is indefinite for failing to recite a final process step which agrees back with the preamble. While minor details are not required in method/process claims, at least the basic steps must be recited in a positive, active fashion. See *Ex parte Elrich*, 3

USPQ2d, p. 1011 (Bd. Pat App. Int. 1986). For example, claims 20 is drawn to a method of fabricating an addressable array of biopolymer probes on a substrate, yet the claim recites a final step of rotating the substrate to a predetermined angular relationship with respect to the dispensing head. The claims do not set forth the conditions/state when the method has provided the addressable array.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-19 rejected under 35 U.S.C. 103(a) as being unpatentable over Blanchard et al. (Biosensors and Bioelectronics 11, 687-690, 1996) in view of Suzuki (U.S. Patent No. 4,675,696, June 23, 1987).

Claims 1-19 is drawn to a method of fabricating an addressable array of biopolymer probes using a deposition apparatus on a substrate according to a target pattern, wherein an error correction step utilizes a fiducial marking on the substrate as a calibration mark for determining the spatial discrepancy between the target array pattern and the actual array pattern, as a means of correcting the target drive pattern. Positional parameters include the position of the substrate and the position of the nozzle.

Budach et al., teach a method for making and using a planar waveguide comprising an array of oligonucleotide probes for hybridization-based assays, wherein the array is produced with a deposition apparatus (see *Ink-Jet Immobilization* starting on page 3349).

Although Budach recognizes resolution-type problems associated with ink jet deposition apparatus (see page 3348, column 1, paragraphs 2 and 3; and the last paragraph of *Spot-to-Spot Reproducibility*), Budach does present a means for correcting the actual array patterns deposited by the apparatus which deviate from the target array pattern wherein a positional correction means is utilized.

Suzuki teaches a recording apparatus with plural recording units, in which a detecting unit detects and corrects the aberration in the recording position by reading a reference pattern formed by the recording units (i.e., imaging a fiducial mark). The

recording apparatus is particularly suitable for depositing a multi-component pattern, as this device/method provides a corrected drive pattern through detecting the error/difference between the actual array pattern and the target array pattern, and calculating the necessary adjustments to the target drive pattern based on substrate and nozzle positions in view of the fiducial mark (see *Detailed Description of the Preferred Embodiments*).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the error correction means of Suzuki with the oligonucleotide deposition method of Budach et al., because Suzuki teaches the benefit of improved ink jet deposition through correcting the target drive pattern through the use of imaging a fiducial mark, and performing the necessary correction in response to the differences in the actual and target array patterns. Furthermore, the use of automated systems (i.e., computer means) for increased method execution speed and improved precision are obvious in view of the teachings of Budach and Suzuki (see M.P.E.P. § 2144.04). Therefore, the invention as a whole was *prima facie* obvious at the time the invention was made.

10. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blanchard et al. (Biosensors and Bioelectronics 11, 687-690, 1996) in view of Sakino et al. (U.S. Patent No. 5,984,470, November 16, 1999).

Claim 20 is drawn to a method of fabricating an addressable array of biopolymer probes using a deposition apparatus on a substrate according to a target pattern,

wherein an error correction step utilizes a fiducial marking on the substrate as a calibration mark for determining the spatial discrepancy between the target array pattern and the actual array pattern, as a means of correcting the target drive pattern. Positional parameters include an angular relationship between the substrate and the nozzle of the deposition apparatus.

Budach et al., teach a method for making and using a planar waveguide comprising an array of oligonucleotide probes for hybridization-based assays, wherein the array is produced with a deposition apparatus (see *Ink-Jet Immobilization* starting on page 3349).

Although Budach recognizes resolution-type problems associated with ink jet deposition apparatus (see page 3348, column 1, paragraphs 2 and 3; and the last paragraph of *Spot-to-Spot Reproducibility*), Budach does present a means for correcting the actual array patterns deposited by the apparatus which deviate from the target array pattern wherein a positional correction means is utilized.

Sakino provides an improvement to the art of ink jet deposition technology, wherein a recognized problem with the actual array pattern suffers from precision-based limitations (see *Summary of the Invention*). Sakino discloses a method/apparatus for a highly precise deposition of micropatterned reagents, which is provided with at least a set of drawing heads for respectively reagents, movement device for moving, with a substrate on which a target pattern is to be formed by drawing with said ink jets, in a plane having a predetermined distance from the drawing heads, displacement detection device for detecting relative displacement between the substrate and the drawing heads

in directions of six degrees of freedom, device for detecting the reaching position on the substrate of the inkjet discharged from the drawing head, and alignment device for effecting alignment between the substrate and the drawing heads in directions of six degrees of freedom, based on the results of detection of the reaching position and of the relative displacement between the substrate and the drawing head indirections of six degrees of freedom, and a fiducial marking(s) are used for alignment/adjustment (see *Detailed Description of the preferred Embodiments*, especially column 11, line 77 to column 12, line 37; and claims 1-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the error correction means of Suzuki with the oligonucleotide deposition method of Budach et al., because Sakino provides an improvement to ink jet deposition apparatus, wherein a fiducial markings are used to provide a corrected drive pattern using angular relationships between the substrate and nozzle. Therefore, the invention as a whole was *prima facie* obvious at the time the invention was made.

Conclusion

11. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeffrey S. Lundgren whose telephone number is (703)

306-3221. The Examiner can normally be reached on Monday-Friday from 7:00 AM to 5:00 PM (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Michael Woodward, can be reached at (703) 308-4028.

Any inquiries of a general nature relating to this application should be directed to the Technology Center Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1631 using (703) 308-0294. Please notify the Examiner of incoming facsimiles prior to sending papers to the aforementioned fax number. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Jeffrey S. Lundgren, Ph.D.

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER